UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UFCW LOCAL 1500 WELFARE FUND, on behalf of itself and all others similarly situated, *Plaintiff*, v. AKORN, INC., FOUGERA PHARMACEUTICALS INC., HI-TECH PHARMACAL CO., INC., MORTON GROVE PHARMACEUTICALS, INC., PERRIGO NEW YORK INC., SANDOZ, INC., TARO PHARMACEUTICALS U.S.A., INC., and WOCKHARDT USA LLC, *Defendants*.	No. _____ CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

1. Plaintiff UFCW Local 1500 Welfare Fund, on behalf of itself and all others similarly situated, brings this class action for claims under federal and state antitrust laws to recover damages and obtain injunctive and equitable relief for the substantial injuries it and others similarly situated have sustained against Defendants arising from their conspiracy to raise the prices of clobetasol propionate topical gel, cream, ointment, solution, and emollient products (collectively, "clobetasol"), as well as to allocate markets and customers for clobetasol in the United States.

2. Plaintiff's claims arise from a broad-based conspiracy by numerous generic drug manufacturers, including Defendants here, to raise and fix the prices of more than a dozen generic drugs, including those at issue in this Complaint.

3. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

NATURE OF THE ACTION

4. Clobetasol is a commonly prescribed medication used to treat skin conditions such as dermatitis and psoriasis. Significantly, this drug is not new: clobetasol was introduced in the 1980s and has been on the market over 30 years.

5. Generic versions of clobetasol have been on the market for years and, for most of that time, have been priced significantly lower than their branded counterparts—in many instances priced at less than a dollar per gram or milliliter (depending on the formulation). This is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers and third-party payors through lower prices.

6. Recently, however, clobetasol has experienced unprecedented price increases. Indeed, since the third quarter of 2014, the price of certain clobetasol formulations has increased ***nearly 1,900%***. The U.S. Government Accountability Office ("GAO") also noted that clobetasol had experienced "extraordinary price increases" between 2010 and 2015.[1]

7. Clobetasol's price hikes were not the result of competitive market forces; instead, they were the result of Defendants' conspiracy to fix, raise, maintain, and stabilize the prices of, as well as allocate customers and markets for, clobetasol.

8. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association ("GPhA"), among others. Oligopolistic conditions—*e.g.*, low numbers of competitors and barriers to entry in the markets for clobetasol—facilitated

[1] *See* GAO, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, App'x III (Aug. 2016), http://www.gao.gov/assets/680/679022.pdf.

Defendants' anticompetitive actions and have allowed them to sustain their unlawful supracompetitive pricing to the present.

9. Defendants' price increases have also grabbed the attention of government enforcers, members of Congress, the press, and drug purchasers. The Department of Justice's Antitrust Division ("DOJ") and the Connecticut Attorney General's Office ("CTAG")—which is leading a multi-state working group of state attorneys general—are conducting sweeping antitrust probes into allegations that as many as a dozen generic drug manufacturers participated in a broad-based conspiracy to fix, raise, maintain, and stabilize the prices of as many as two-dozen generic drugs. Significantly, DOJ has issued subpoenas which arise from a federal grand jury proceeding in the Eastern District of Pennsylvania that is investigating whether Defendants and other drug manufacturers conspired to fix generic drug prices.

10. For example, in September 2016, Taro, which manufactures clobetasol, disclosed that it, "as well as two senior officers in its commercial team, received grand jury subpoenas from the [DOJ]," seeking, among other things, "communications with competitors and others regarding the sale of generic pharmaceutical products."[2]

11. The government investigations into generic drug manufacturers' pricing behavior go beyond just clobetasol. DOJ and CTAG have issued subpoenas seeking information about their pricing of multiple other generic products to several other generic drug manufacturers including: Impax, Lannett, Par, Actavis, Mayne Pharma, Mylan, Teva, and Zydus.

12. The DOJ's investigation could also result in the imposition of substantial fines against many generic drug manufacturers, including those named as Defendants here. One

[2] Taro, SEC Form 6-K (Sept. 9, 2016), http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjUwJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3.

analyst has estimated, for example, that Teva could face liability of between $300 million and $700 million, while Mylan could face liability of between $380 million and $770 million. Another analyst estimated that fines industry-wide could exceed $1 billion.[3]

13. In addition to DOJ's and CTAG's investigations, members of Congress have written letters to generic manufacturers Actavis, Apotex, Impax, Lannett, Mylan, Par, Sun, Teva, West-Ward, and Zydus, requesting information concerning their sales of numerous generic drugs, including albuterol sulfate, glycopyrrolate, neostigmine methylsulfate, and benazepril/ hydrochlorothiazide.

14. Significantly, recent news reports have stated that investigations are on the cusp of the prosecution phase: *Bloomberg*, *The Wall Street Journal*, and *Reuters* have all reported that, after two years of investigation, DOJ is close to bringing criminal charges against generic drug manufacturers, with sources stating that the charges could be brought as early as the end of 2016.[4]

15. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of clobetasol, consumers and third-party payors paid, and continue to pay, supracompetitive prices for these generic drugs.

16. Plaintiff seeks to certify two classes. The first class (the "Injunctive Class") is composed of all individuals and entities in the United States or its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for clobetasol,

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[3] Eric Saonowsky, *DOJ's price-fixing investigation could lead to sizable liabilities, analyst says*, FiercePharma (Nov. 10, 2016), http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says.

[4] *See* David McLaughlin & Caroline Chen, *U.S. Charges in Generic-Drug Probe to Be File by Year-End*, Bloomberg (Nov. 3, 2016), http://bloom.bg/2fIr5rX; Peter Loftus, et al., *Generic-Drug Firms Face Possible Collusion Charges*, Wall St. J. (Nov. 3, 2016), http://www.wsj.com/articles/generic-drug-makers-shares-drop-on-report-of-possible-probe-1478209036; Deena Beasley, *Drug makers under fire for possible price fixing*, Reuters (Nov. 3, 2016), http://reut.rs/2fIIPn0.

other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as June 3, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Class Period").

17. The second class (the "Damages Class") is composed of all individuals and entities who, in Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia, indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for clobetasol, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as June 3, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

JURISDICTION AND VENUE

18. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. §26, to obtain injunctive relief and costs of suit, including attorneys' fees, against Defendants for the injuries that Plaintiff and the other members of the Injunctive Class have suffered from Defendants' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 16 of the Clayton Act, 15 U.S.C. § 26, because this action arises under the federal antitrust laws. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

20. This Court also has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the

proposed class exceeds $5,000,000 and at least one member of the Damages Class is a citizen of a state different from that of one of Defendants.

21. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), and (d) and Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

22. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

23. Defendants sold and shipped clobetasol in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate and intrastate commerce.

24. Each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

THE PARTIES

A. Plaintiff

25. Plaintiff UFCW Local 1500 Welfare Fund ("**Local 1500**") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York, 11590. Local 1500 provides nearly 23,000 members with health and welfare benefits, many of whom live in New York, among other states. During the Class Period, Local 1500 purchased and paid for some or all the purchase price for clobetasol, thereby suffering injury to its business and property. Local 1500 paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

B. Defendants

1. Akorn Defendants

26. Defendant Akorn, Inc. is a Louisiana corporation with is principal place of business at 1925 W. Field Court, Suite 300, Lake Forest, Illinois, 60045.

27. Defendant Hi-Tech Pharmacal Co., Inc. is a New York-based pharmaceutical company with its principal place of business at 369 Bayview Avenue, Amityville, New York, 11701. Hi-Tech Pharmacal Co., Inc. became a subsidiary of Akorn, Inc. in April 2014, when Akorn, Inc. completed its acquisition of Hi-Tech Pharmacal Co., Inc. for $640 million.

28. Defendants Akorn Inc. and Hi-Tech Pharmacal Co., Inc. are collectively referred to as "**Akorn**." Akorn manufactures, markets, and sells branded and generic pharmaceutical products. During the Class Period, Akorn sold generic clobetasol in the United States.

2. Perrigo

29. Defendant Perrigo New York Inc. ("**Perrigo**") is a Delaware corporation with its principal place of business located at 1700 Bathgate Avenue, Bronx, New York, 10457. Perrigo is a subsidiary of Perrigo Company plc, an Irish company with its principal place of business located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland. During the Class Period, Perrigo sold generic clobetasol in the United States.

3. Sandoz Defendants

30. Defendant Sandoz, Inc. is a Colorado corporation with its principal place of business located at 100 College Road, Princeton, New Jersey, 08540. Sandoz, Inc. is a global leader in generic pharmaceuticals and biosimilars and a division of the Novartis Group.

31. Defendant Fougera Pharmaceuticals Inc. is a New York corporation with its principal place of business located at 60 Baylis Road, Melville, New York, 11747. Fougera is a

wholly-owned subsidiary of Sandoz, Inc., specializing in the production, marketing, and sale of dermatological products.

32. Defendants Sandoz, Inc. and Fougera Pharmaceuticals Inc. are collectively referred to as "**Sandoz**." Sandoz manufactures, markets, and sells generic pharmaceutical products in the United States. During the Class Period, Sandoz sold generic clobetasol in the United States.

4. Taro

33. Defendant Taro Pharmaceuticals U.S.A., Inc. ("**Taro**") is a corporation with its principal place of business at Three Skyline Drive, Hawthorne, New York 10532. Taro is a subsidiary of Taro Pharmaceuticals Industries Ltd., an Israeli company with its principal place of business at 14 Hakitor Street, PO Box 10347, Haifa Bay, 2624761, Israel. Taro Pharmaceuticals Ltd., in turn, is a subsidiary of Sun Pharma. Taro manufactures, markets, and sells branded and generic pharmaceutical products. During the Class Period, Taro sold generic clobetasol in the United States.

5. Wockhardt Defendants

34. Defendant Wockhardt USA LLC is a New Jersey-based corporation with its principal place of business located at 20 Waterview Blvd., Parsippany, New Jersey, 07054.

35. Defendant Morton Grove Pharmaceuticals, Inc. is an Illinois-based corporation with its principal place of business located at 6451 West Main Street, Morton Grove, Illinois, 60053.

36. Defendants Wockhardt USA LLC and Morton Grove Pharmaceuticals, Inc. are collectively referred to as "**Wockhardt**." Wockhardt manufactures, markets, and sells generic pharmaceutical products. During the Class Period, Wockhardt sold generic clobetasol in the United States.

37. Defendants Akorn, Perrigo, Taro, Sandoz, and Wockhardt are referred to collectively as "**Defendants**."

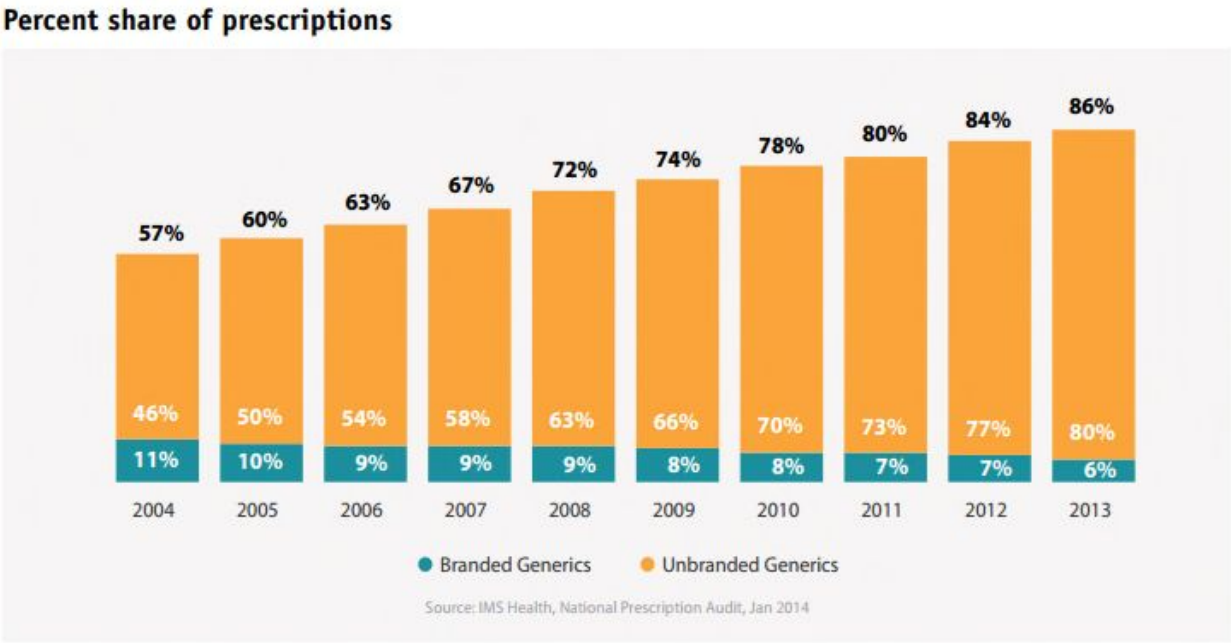
38. Various other entities and individuals unknown to Plaintiff at this time participated as co-conspirators in the acts complained of, and performed acts and made statements that aided and abetted and were in furtherance of the unlawful conduct alleged herein.

GENERIC DRUGS REDUCE PRESCRIPTION DRUG COSTS TO PATIENTS AND THIRD-PARTY PAYORS

39. When generic versions of a branded drug—whether a generic manufactured and sold by an independent generic manufacturer or an "authorized generic," or "branded generic," sold by or pursuant to an agreement with the branded manufacturer—enter the market, they quickly gain substantial market share.

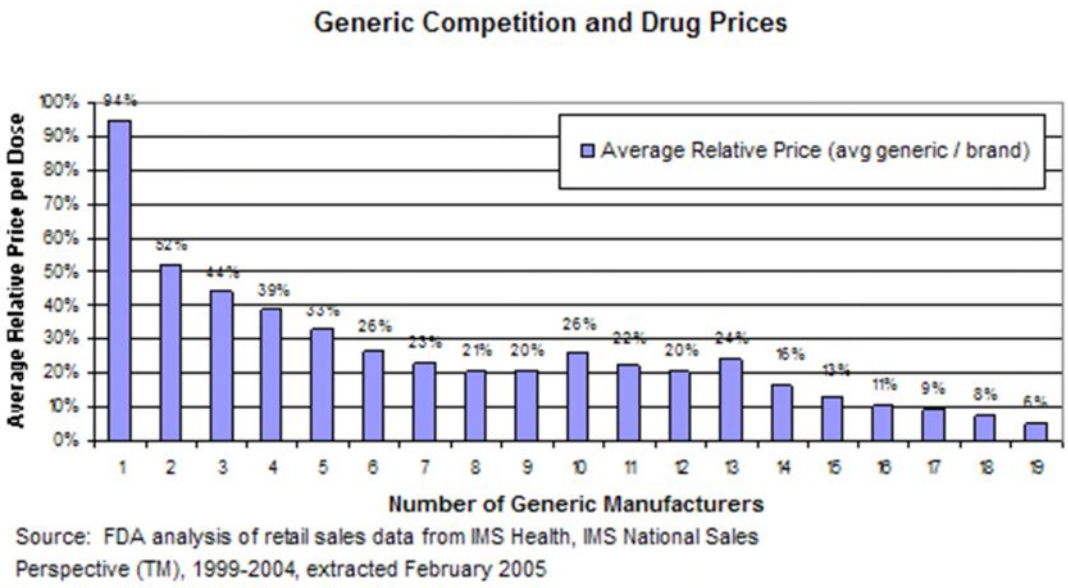
40. Empirical studies have shown that within a year of generic entry, generics typically will have obtained about 90% of the market, *i.e.*, pharmacists will fill 90 of every 100 prescriptions with a generic. Indeed, according to IMS Health data, generic drugs as a whole have increased the share of total prescriptions steadily since 2004, and as of 2013, account for 86% of all drugs dispensed in the United States.[5]

[5] IMS Institute for Healthcare Informatics, Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013 (Apr. 2014), at 51, http://www.plannedparenthoodadvocate.org/2014/IIHI_US_Use_of_Meds_for_2013.pdf.



41. When generic drugs are launched, they are typically priced below the prices of their branded counterparts. Indeed, in a competitive market, each successive generic product that enters the market lowers the prices of all similar generic products because each entry increases competition for sales and market share. A Food and Drug Administration ("FDA") study demonstrates this effect in the following chart:[6]

[6] FDA, Generic Competition and Drug Prices, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

42. More recent evidence obtained by the GAO suggests that each subsequent generic entrant drives the price down by 20%.

43. A Federal Trade Commission study confirmed the FDA's analyses, finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[7]

44. Thus, generic competition to even a single brand drug can potentially provide billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers, health and welfare funds, and state Medicaid programs, which reimburse the cost of drug purchases by covered individuals. Indeed, one study found that the use of generic medicines saved the U.S. healthcare system $254 billion in 2014 alone, and $1.68 trillion between 2005 and 2014.[8]

[7] FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* http://emmanuelcombe.org/delay.pdf.

[8] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

45. These consumer welfare-enhancing attributes of generic drug competition were bolstered by the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act." The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and costly New Drug Application ("NDA"), the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application ("ANDA").

46. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug's NDA, including safety and efficacy data. The ability to rely on the scientific data published in the referenced brand drug's NDA obviates the need for duplicative and expensive experimentation and clinical trials. The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.

47. In connection with the approval of a generic drug, the FDA will assign a "Therapeutic Equivalence Code" ranging from "AA" to "BX." An "AB" rating signifies that the approved generic product is therapeutically equivalent to its branded counterpart. An AB rating is significant because under state generic drug substitution laws, pharmacists are permitted—and, in many cases, must—substitute the branded product for its cheaper generic counterpart. Moreover, in about 20 states, non-AB rated generic drugs can be substituted for their branded counterparts subject to certain considerations, including informed consent from patient or

physician and whether the switch is appropriate in a pharmacist's professional judgment.[9] This inures to the financial benefit of consumers and third-party payors.

48. In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

FACTUAL BACKGROUND FOR CLOBETASOL

49. Clobetasol is a "super-potent" (Class 1) corticosteroid of the glucocorticoid class used to treat various skin disorders including eczema and psoriasis. Clobetasol has been marketed since at least 1985.

1. Branded Clobetasol

50. GlaxoSmithKline ("GSK") developed and marketed clobetasol under the brand name Temovate® in the mid-1980s. By the mid-1990s, the FDA had approved five versions of Temovate:

(a) Topical cream (NDA 019322, approved December 27, 1985);

(b) Topical ointment (NDA 019323, approved December 27, 1985);

(c) Topical solution (NDA 019966, approved February 22, 1990);

(d) Topical gel (NDA 020337, approved April 29, 1994); and

(e) Topical emollient (NDA 020340, approved June 17, 1994).

51. All forms of Temovate have since been discontinued. However, generic versions of Temovate are still available.

[9] http://pharmacistsletter.therapeuticresearch.com/pl/ArticleDD.aspx?nidchk=1&cs=&s=PL&pt=2&segment=1186&dd=220901&AspxAutoDetectCookieSupport=1.

2. Generic Manufacturers of Clobetasol

52. Akorn, Perrigo, Sandoz, Taro, and Wockhardt are among the generic drug manufacturers that currently market generic versions of clobetasol.

(a) Akorn has manufactured generic versions of clobetasol since receiving FDA approval in March 1995 for its topical ointment formulation. Akorn later received FDA approval for topical solution, cream, emollient, and gel formulations in December 1995, May 1997, December 1998, and April 2002, respectively. When these ANDAs were first approved, Akorn's predecessors marketed these clobetasol products under different trade names. For example, Cormax was used for clobetasol cream; Embeline was used for clobetasol ointment, solution, and gel; and Embeline-E was used for clobetasol emollient. Today, however, these trade names are no longer used.

(b) Perrigo has manufactured generic versions of clobetasol since receiving FDA approval in October 1997 for its topical gel formulation.

(c) Sandoz has manufactured generic versions of clobetasol since receiving FDA approval for its topical ointment and cream formulations in February 1996 and September 1996, respectively. Sandoz later received FDA approval for its topical solution, emollient, and gel formulations in February 1999, May 1999, and February 2000, respectively.

(d) Taro has manufactured generic versions of clobetasol since receiving FDA approval for its topical cream and ointment formulations in July 1996. Taro later received FDA approval topical solution, gel, and emollient formulations in November 1998, May 1999, and May 2000, respectively.

(e) Wockhardt has manufactured generic versions of clobetasol since receiving FDA approval for its topical solution in November 1998.

53. Smaller players in the clobetasol market include Actavis, Novel Laboratories, and G&W Laboratories. Actavis and Novel both launched their clobetasol products in 2015. In Actavis's case, it marked a re-entry into the clobetasol market, having exited it years earlier, along with other manufacturers including Teva and Glenmark.[10] G&W Laboratories maintains ANDAs for a number of clobetasol products (ointment, cream, and solution), but does not appear to have actively marketed clobetasol until more recently in 2016, with clobetasol ointment.

DEFENDANTS' WRONGDOING

54. As part of their conspiracy, Defendants agreed to raise prices of clobetasol sold in the United States. Between 2009 and June 2015, industry consolidation limited the number of generic drug manufacturers producing and selling clobetasol to just over a handful of companies—namely, Defendants Akorn, Perrigo, Sandoz, Taro, and Wockhardt. Even among these manufacturers, most sales were concentrated in the hands of three companies: Akorn, Sandoz, and Taro, which had a combined market share in excess of 75%.[11]

55. As with various other drugs under investigation by the DOJ, trade association meetings provided Defendants with the means and the opportunity to conspire to fix and raise clobetasol prices and allocate markets and customers for clobetasol. For example, representatives from Akorn, Perrigo, Sandoz, Taro, and Wockhardt attended a GPhA CMC Workshop in North Bethesda, Maryland between June 3 and June 4, 2014. Shortly after this meeting, each clobetasol manufacturer raised its respective clobetasol prices dramatically; prices of clobetasol topical

[10] Anubhav Aggarwal & Chunky Shah, Credit Suisse: Taro Pharma, at 3 (June 27, 2014).

[11] Anubhav Aggarwal & Chunky Shah, Credit Suisse – Asia Daily: Taro Pharma, at 1 (May 5, 2015), https://doc.research-and-analytics.csfb.com/docView?language=ENG&format=PDF&document_id=1048063721&source_id=emcsplus&serialid=gEWd6KxxrSPx2oTPHLxatrBIVf%2BeWeISMfxnRIAsaQU%3D.

cream, one clobetasol formulation, which were around $0.27 per gram just prior to the CMC Workshop meeting, soared to over $4.16 per gram by 2015—an increase of ***over 1,400%***.[12]

56. On a second quarter 2014 earnings call, Akorn's CEO Raj Rai, explained that Akorn raised its clobetasol prices after a generic competitor raised its clobetasol prices.[13] Strikingly, Akorn did not see price increases by competitors as an opportunity to cut its own prices in attempt to gain market share. Indeed, when asked by an analyst on that same earnings call, "[H]ow did you decide to match versus maybe coming in at a slightly lower price point in an attempt to pick share," Mr. Rai would not explain in any detail why his company would act against its own economic interest. Rather, he simply responded:

> We are not going to share our . . . details of the strategy as to how we price product ***but you got to be competitive and you got to sometimes follow what the competitors are doing***. So, that's exactly what happened here, so I think I will just leave it to that.[14]

57. But Akorn's pricing behavior with regard to clobetasol was anything but "*competitive*." Indeed, its pricing indicates an anticompetitive marketplace. In a competitive market, firms will *cut* prices to increase sales volumes and market share. Akorn's decision to increase prices in the face of a competitor's price increases is not a pro-competitive response. Instead, it suggests collusion.

58. The Center for Medicare & Medicaid Service's National Average Drug Acquisition Cost ("NADAC") data shows that the price movements for clobetasol were far above competitive levels, and thus, suggestive of a conspiracy to raise clobetasol prices. The

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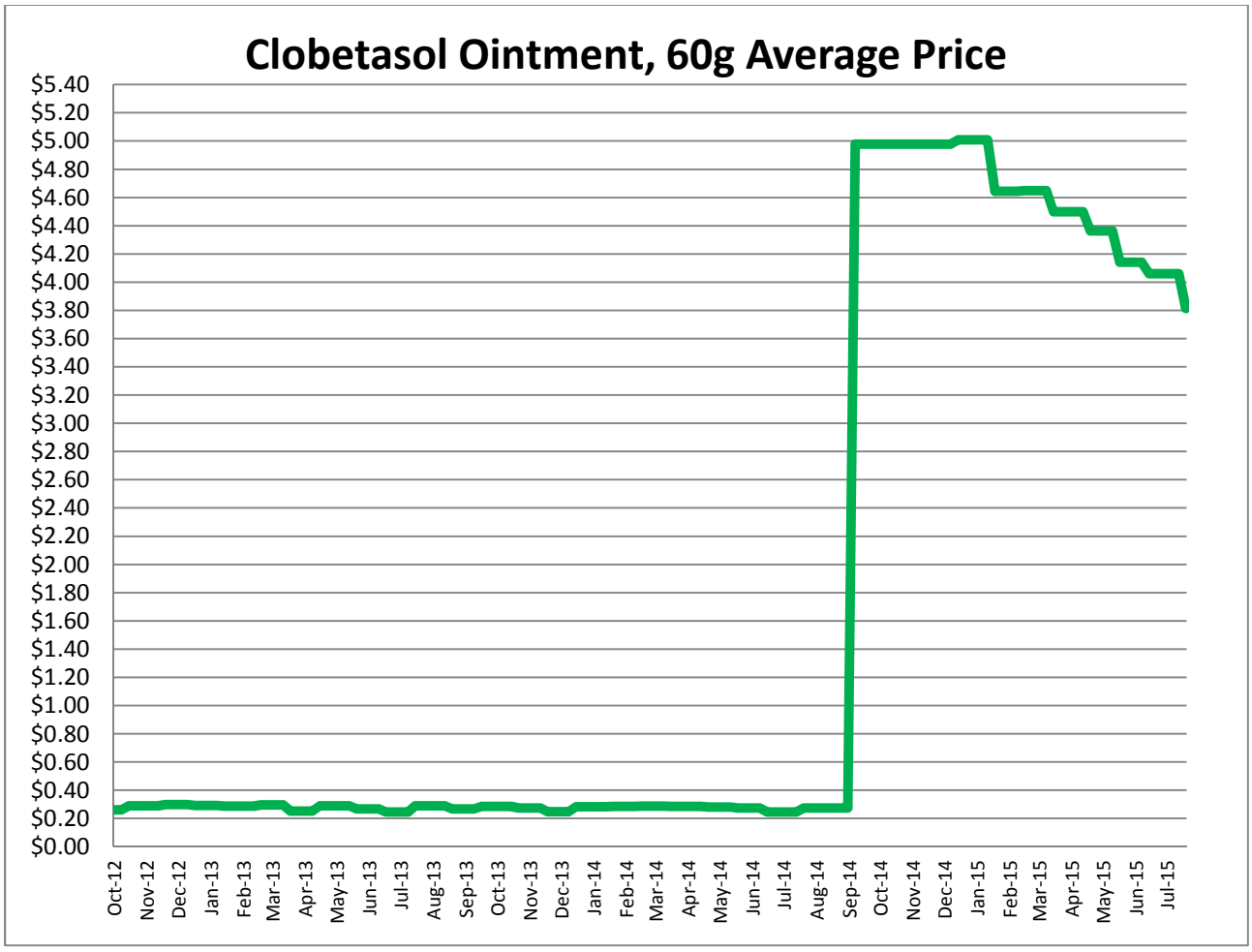
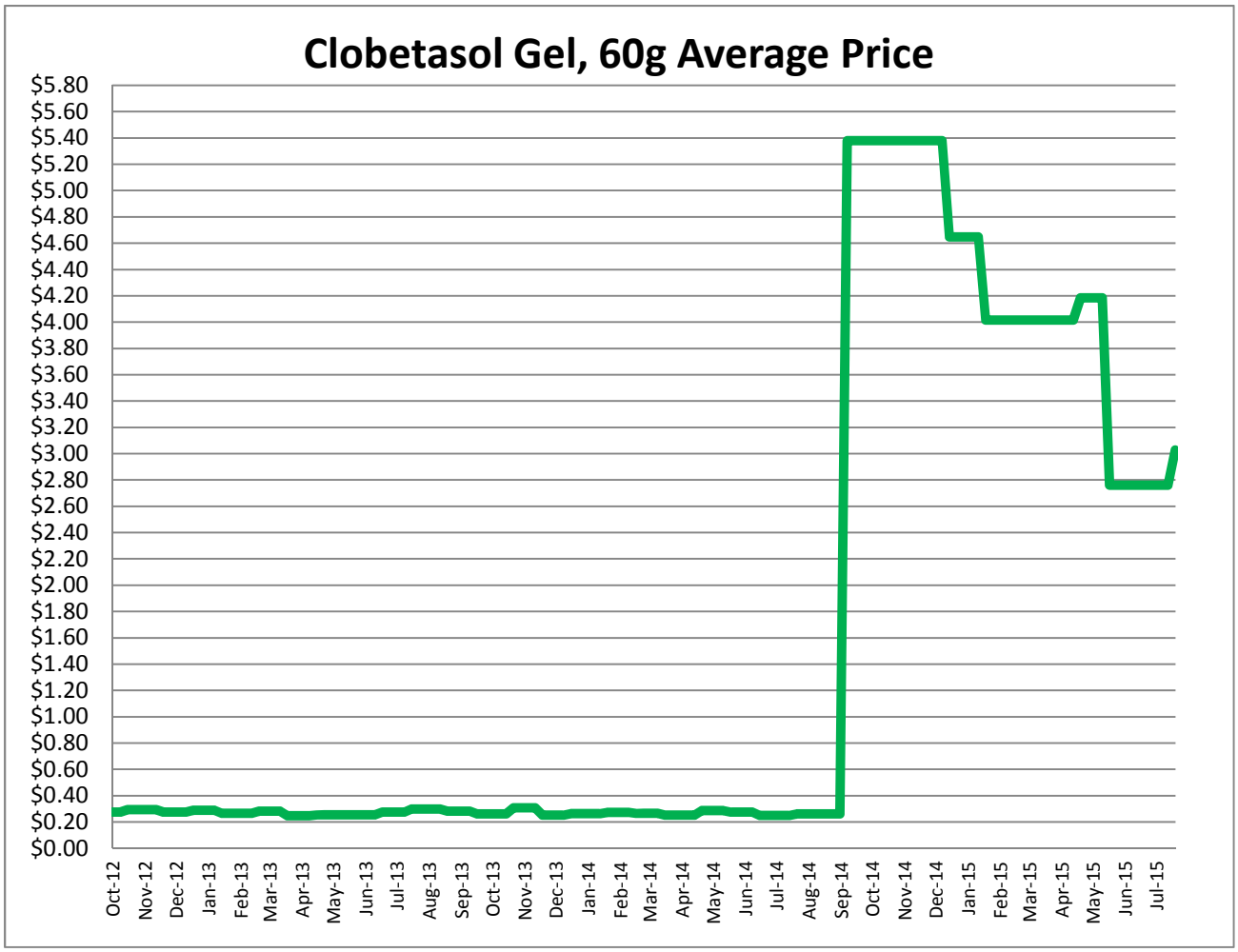
[12] Priyanka Dayal McCluskey, *As competition wanes, prices for generics skyrockets*, Boston Globe (Nov. 6. 2015), https://www.bostonglobe.com/business/2015/11/06/generic-drug-price-increases-alarm-insurers-providers-and-consumers/H3iA9CSxAUylnCdGjLNKVN/story.html.

[13] http://seekingalpha.com/article/2384615-akorns-akrx-ceo-raj-rai-on-q2-2014-results-earnings-call-transcript?part=single.

[14] *Id.*

charts below show the average price per unit of generic clobetasol topical ointment (60g), gel (60g), cream (60g), solution (50mL), and emollient (60g) between October 2012 and July 2015:




Clobetasol Gel, 60g Average Price
$5.80
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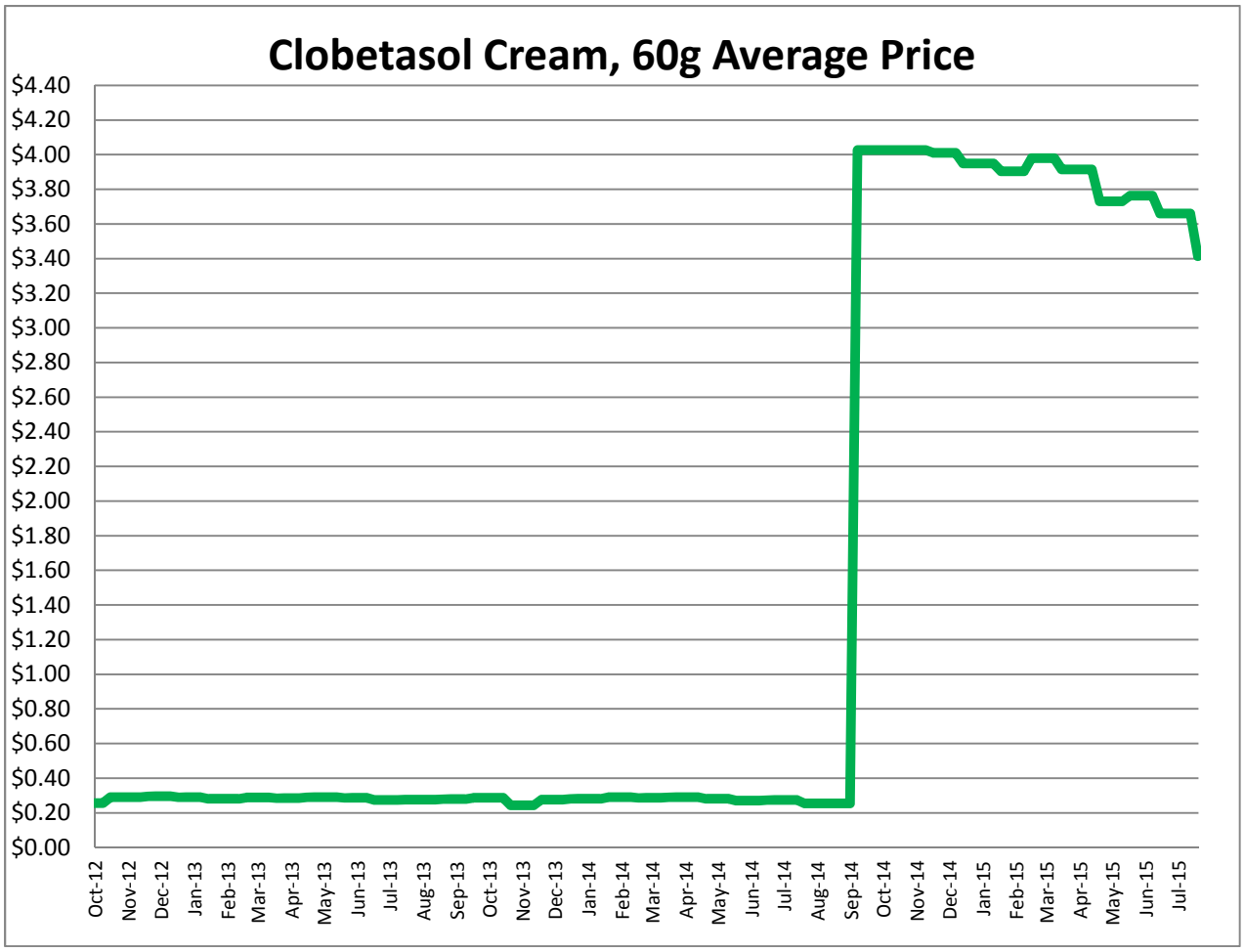
Clobetasol Cream, 60g Average Price
$4.40
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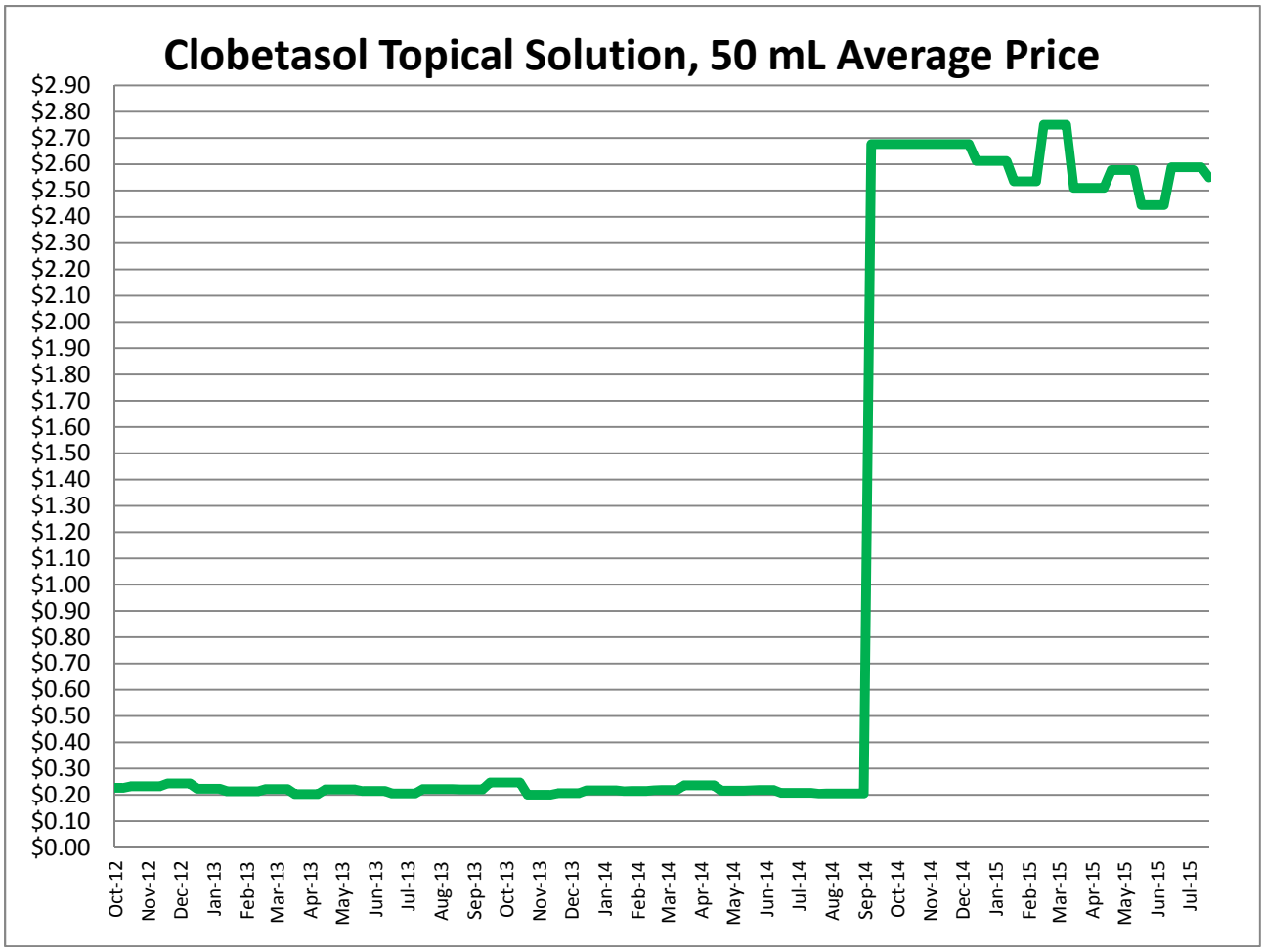
Clobetasol Topical Solution, 50 mL Average Price
$2.90
$2.80
$2.70
$2.60
$2.50
$2.40
$2.30
$2.20
$2.10
$2.00
$1.90
$1.80
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Oct-12
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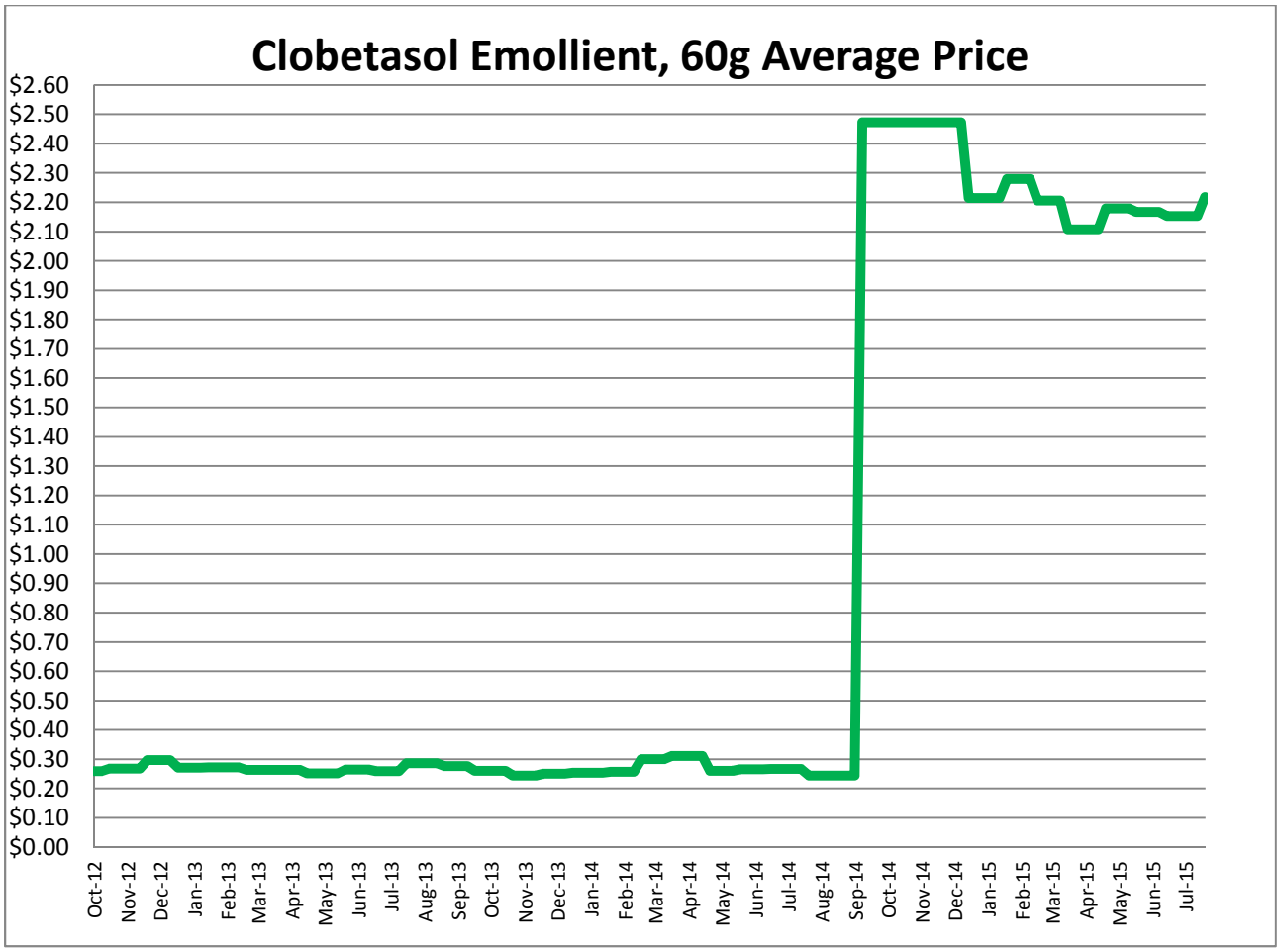

59. As seen in the charts above, between October 2012 and June 2014, clobetasol prices were relatively stable—typically below $0.30 per gram or milliliter, depending on the formulation. However, after June 2014, when Defendants attended the GPhA CMC Workshop, clobetasol prices rose from under $0.30 per unit in July 2014 to between $2 and $5 per unit in September 2014. The table below shows the price increases for the clobetasol topical ointment, gel, cream, solution, and emollient formulations.

Clobetasol Product	*NADAC per Unit Price (May 2014)*	*NADAC per Unit Price (September 2014)*	*Percent Change in NADAC per Unit Price*
0.05% ointment, 60g	$0.27	$4.98	**1,744.4%**
0.05% gel, 60g	$0.27	$5.38	**1,892.6%**
0.05% cream, 60g	$0.27	$4.03	**1,392.6%**
0.05% solution, 50mL	$0.22	$2.68	**1,118.2%**
0.05% emollient, 60g	$0.27	$2.47	**814.8%**

60. For clobetasol producers, this generated an enormous windfall of revenue—Akorn, for example, recorded nearly $100 million in clobetasol sales after increasing prices in August 2014.

61. Further, although clobetasol prices have eroded somewhat, they still remain substantially above the pre-June 2014 prices. Even the entry in 2015 by Actavis for clobetasol cream and Novel Laboratories for clobetasol topical solution have not had any appreciable effect on the prices of these clobetasol products. In fact, as noted above, upon entering the market, Actavis matched incumbents' prices rather than attempting to undercut them. During a third quarter 2016 earnings call, Akorn's CEO noted that despite some price erosion, Akorn and its competitors are still reaping the outsized profits from their illicit scheme: "[O]verall, derms [dermatological drugs] is a good place to be in and still limited competition."[15]

62. Defendants' coordinated pricing has deprived, and continues to deprive, Plaintiff and members of the Classes the benefits of free and open competition—namely, lower prices for

[15] http://seekingalpha.com/article/4018961-akorn-akrx-q3-2016-results-earnings-call-transcript?part=single.

generic versions of clobetasol. As a result, Plaintiff and members of the Classes have paid and continue to pay non-competitive prices for clobetasol.

A. Defendants' Conspiratorial Conduct to Fix Prices and Allocate Customers and Markets for Generic Clobetasol

63. There are no market-based reasons for the pricing patterns in the clobetasol market.

64. Rather, Defendants sustained these supracompetitive profits by conspiring to fix, raise, maintain, and stabilize the prices of, and allocate markets and customers for clobetasol. The price increases were the product of Defendants' shared desire to extract monopoly rents from captive drug purchasers.

65. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

(a) Attending joint meetings or otherwise engaging in joint discussions in the United States by telephone, facsimile, and electronic mail regarding the sale of clobetasol;

(b) Agreeing to charge prices for clobetasol at specified levels, and otherwise fix, increase, maintain, and stabilize the prices and supply of clobetasol sold to purchasers in the United States;

(c) Selling clobetasol to customers in the United States at collusive and non-competitive prices pursuant to the agreements reached;

(d) Accepting payments for clobetasol sold in the United States at collusive and non-competitive prices;

(e) Communicating with one another to discuss the prices, customers, markets, supply and manufacturing issues, and price levels of clobetasol sold in the United States;

(f) Authorizing or consenting to the participation of employees in the conspiracy; and

(g) Concealing the conspiracy and conspiratorial contacts through various means.

66. The purpose of these secret, conspiratorial meetings, discussions, and communications was to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful price-fixing and market and customer allocation scheme.

67. As a result of Defendants' unlawful agreement to restrain trade, Plaintiff and members of the Classes were injured because they paid, and continue to pay, supracompetitive prices for clobetasol sold in the United States during the period June 3, 2014 through the present.

THE GENERIC MARKET FOR CLOBETASOL IS SUSCEPTIBLE TO A PRICE FIXING CONSPIRACY

A. Factors Supporting the Existence of a Conspiracy in the Clobetasol Market

68. The structure and other characteristics of the market for clobetasol make it conducive to collusion and price-fixing. Specifically, during the Class Period, the clobetasol market exhibited: (1) high barriers to entry; (2) inelasticity of demand; (3) a high degree of commoditization; (4) a high degree of concentration; (5) competitors acting against their economic self-interest; (6) lack of significant competitors who could discipline Defendants' collusive pricing; and (7) opportunities to conspire.

1. There Are High Barriers to Entry in the Markets for Generic Drugs, Including Clobetasol

69. A collusive arrangement that raises product prices above competitive levels would, under basic economic principles, attract new entrants seeking to benefit from the supra-competitive pricing. When, however, there are significant barriers to entry, new entrants are

much less likely to enter the market. Thus, barriers to entry help facilitate the formation and maintenance of a cartel.

70. The clobetasol market has high barriers to entry.

71. Even though clobetasol is not protected by any patents, regulatory hurdles and the costs of doing business make market entry difficult, time consuming, and expensive. Any generic drug manufacturer seeking to enter the clobetasol market must file an ANDA and receive FDA approval.

72. To file an ANDA, the generic manufacturer must show that the generic product is bioequivalent to its branded counterpart and invest considerable resources in the development of production lines capable of making the drug. Historically, the cost of filing an ANDA is about $1 million.[16] A generic manufacturer's production facilities must also meet CGMP standards, which increase the costs of production.

73. Moreover, a generic manufacturer that cannot produce the Active Pharmaceutical Ingredient ("API") for clobetasol must have a reliable and affordable source of API for these products.

74. Prospective generic manufacturers must also be able to satisfy FDA regulations and guidance governing bioequivalence and bioavailability of their clobetasol products. This requires showing that the proposed generic clobetasol products have, among other things, the same therapeutic qualities and absorption profiles as their branded counterparts.

[16] Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), at 7.

75. The failure to meet all FDA requirements concerning manufacturing, testing, and labeling of clobetasol will result in the FDA delaying (or denying) approval of an ANDA. These delays can last for months or even years.

76. Even if a non-conspiring generic manufacturer were to see an opportunity to compete on price regarding clobetasol, due to the fact that the FDA's review of ANDAs is currently significantly "backlogged," any potential entrant would necessarily be delayed for years.[17] Indeed, the FDA has stated that as of fiscal year 2015, ANDA approvals can take 40 months or more.[18]

2. Demand for Clobetasol Is Inelastic

77. "Elasticity" is a term used to describe the sensitivity of supply and demand to changes in one or the other. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

78. For a cartel to profit from raising prices above competitive levels, demand must be relatively inelastic at competitive prices. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

79. Demand for clobetasol is highly inelastic because it is a unique product for which there are no reasonable substitutes.

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[17] *Id.* at 7.

[18] GAO, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, at 26 (Aug. 2016), http://www.gao.gov/assets/680/679022.pdf.

80. Clobetasol is a "super-potent" (Class 1) topical corticosteroid of the glucocorticoid class. It is indicated to treat a variety of skin conditions, including psoriasis. Even among other Class 1 topical corticosteroids—*e.g.*, betamethasone dipropionate, halobetasol propionate, and diflorasone—clobetasol has a unique active ingredient, chemistry, and pharmacokinetics. Thus, there are no reasonable substitutes that are therapeutically equivalent.

81. Thus, purchasers of clobetasol are held captive to the supracompetitive prices that resulted from Defendants' conspiracy to fix prices and allocate markets and customers.

3. Clobetasol Is a Commodity Product

82. When products are subject to commoditization, producers of those products are usually forced to compete on price, as opposed to other factors, such as quality and ancillary services. When price becomes a significant factor in driving demand for a product, producers of a commoditized product have an easier time colluding on price than other non-price factors because price-based collusion is much easier to implement and monitor.

83. Generic drugs of the same chemical composition are effectively commodity products because the primary mechanism through which they compete is price. Indeed, state laws require that pharmacists substitute available AB-rated generic drugs for their branded counterparts precisely because of their lower price. Defendants' clobetasol products are AB-rated generics to their branded counterparts, enabling substitution.

84. Moreover, because generic manufacturers generally spend little effort advertising or detailing their generic compounds (*i.e.*, the practice of providing promotional materials and free samples to physicians), the primary means for one generic manufacturer to differentiate its

product from another generic competitor's product is through price reductions.[19] The need to compete on price can drive producers of commodity products to conspire—as they did here—to fix prices.

4. The Generic Clobetasol Market Is Highly Concentrated

85. A concentrated market is more susceptible to collusion and other anticompetitive practices.

86. The clobetasol market is highly concentrated, with only a handful of companies dominating the market—Sandoz, Akorn, Perrigo, Taro, and Wockhardt. Even within this group, Akorn, Sandoz, and Taro collectively had the lion's share of the market.

87. The limited number of clobetasol manufacturers facilitated those manufacturers' ability to coordinate pricing of their respective products. This concentration also made it easy for them to monitor prices in the downstream market and police deviations from agreed-upon prices.

88. As the dominant players in the market for clobetasol, Defendants were able to fix, raise, and maintain their prices on these products without competitive threats from rival generic drug manufacturers.

5. Defendants' Pricing of Clobetasol Was Against Their Self-Interest

89. Competitive firms in a competitive, commoditized marketplace will typically price their products aggressively, relative to their competitors' products. Firms price aggressively with the understanding that if they do not do so, other competitors will undercut their relatively high price, taking sales—and ultimately market share—away from the firms that are pricing less aggressively.

[19] *See* Congressional Budget Office, Promotional Spending for Prescription Drugs, Economic & Budget Issues Brief (Dec. 2, 2009), at 1.

90. Here, however, rather than attempt to take sales, revenue, and market share away from one another, Defendants instead sought to meet the price increases made by others and extract supracompetitive prices from Plaintiff and members of the Classes.

91. As alleged above, Akorn did just that for clobetasol—it raised its prices in response to price increases by its competitors. Moreover, Akorn's CEO could not explain why Akorn would forego the obvious gains in market share, sales volume, and revenue, if it had simply cut prices in response to its competitors' price increases.

92. Such conduct was against each Defendant's self-interest because rather than cut prices to gain sales, revenues, and market share, each Defendant instead sought to sacrifice these potential gains in favor of cartel pricing. Defendants' individual failures to cut prices in the face of price increases from competitors suggests that Defendants were conspiring to fix and raise prices, rather than competing on price.

6. Other Clobetasol Manufacturers Could Not Constrain Defendants' Pricing

93. Cartels need not require the participation of all potential competitors in order to be effective. Where a market is dominated by a few firms, the pricing of these firms may not be disciplined even by the presence of other, smaller competitors. Indeed, these smaller competitors may tacitly join any collusive pricing set by the dominant firms.

94. The clobetasol market, as noted above was dominated by a few firms—namely, Akorn, Perrigo, Sandoz, Taro, and Wockhardt. Fringe and newer competitors, such as Actavis, G&W Laboratories, and Novel Laboratories, did not discipline the supracompetitive pricing. Indeed, in the case of Actavis, new competitors actually matched the prices of the incumbents rather than undercut them.

7. Memberships in the Same Trade Associations Provided Defendants with Opportunities to Conspire

95. To sustain a conspiracy, the conspirators must periodically communicate to ensure that all are adhering to the collective scheme.

96. Defendants were members of trade associations, which they used to facilitate their conspiratorial communications and implement their price-fixing scheme, including but not limited to the largest association of generic pharmaceutical manufacturers, GPhA.

97. Current "Regular Members" of GPhA include Defendants Perrigo, Sandoz, and Wockhardt. To be a Regular Member, a company must derive the majority of its revenues from sales of generic drugs (whether drugs approved through the ANDA process, authorized generic drugs, biosimilar products, or DESI products).

98. Some of Defendants' high-ranking officers also serve on GPhA's Board of Directors, including: Perrigo's Richard Stec and Sandoz's Peter Goldschmidt.

99. Defendants' representatives attended many meetings held by GPhA, including the following between 2013 and 2015:

Meeting	Meeting Date and Location	Attendees
2013 GPhA Annual Meeting	February 20-22, 2013, Orlando, Florida	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2013 GPhA CMC Workshop	June 4-5, 2013, Bethesda, Maryland	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2013 GPhA Fall Technical Conference	October 28-30, 2013, Bethesda, Maryland	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2014 GPhA Annual Meeting	February 19-21, 2014, Orlando, Florida	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2014 GPhA CMC Workshop	June 3-4, 2014, Bethesda, Maryland	Akorn, Perrigo, Sandoz, Taro, Wockhardt

Meeting	Meeting Date and Location	Attendees
2014 GPhA Fall Technical Conference	October 27-29, 2014, Bethesda, Maryland	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2015 GPhA Annual Meeting	February 9-11, 2015, Miami Beach, Florida	Akorn, Perrigo, Sandoz, Taro, Wockhardt
2015 GPhA CMC Workshop	June 9-10, 2015, Bethesda, Maryland	Perrigo, Sandoz, Taro, Wockhardt
2015 GPhA Fall Technical Conference	November 2-4, 2015, Bethesda, Maryland	Akorn, Perrigo, Sandoz, Taro

100. Thus, it is not surprising that, according to public reports, DOJ's criminal probe is focused on trade associations, including GPhA, because these trade associations may have been used by Defendants' sales representatives to coordinate and implement their anticompetitive scheme. As noted above, certain of Defendants' representatives held senior positions at the GPhA.

101. Upon information and belief, Defendants' employees discussed their anticompetitive scheme to raise, maintain, and stabilize the prices of clobetasol, as well as other drugs, and how to allocate markets and customers, at these meetings, among others.

GOVERNMENT INVESTIGATIONS INTO GENERIC DRUG PRICING

A. Congressional Investigations into Generic Drug Pricing

102. As news reports have proliferated with respect to the dramatic rise in price of certain generic drugs, members of Congress have expressed a growing concern as to what is driving these price hikes. On October 2, 2014, Representative Elijah E. Cummings, the Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, "sent letters to 14 drug manufacturers requesting

information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses."[20]

103. These letters were delivered to the heads of Actavis, Apotex, Dr. Reddy's, Impax, Mylan, Par Pharmaceutical, Teva, Zydus, Endo, Heritage Pharmaceuticals, and Marathon Pharmaceuticals, seeking information about the pricing of divalproex ER, pravastatin, digoxin, doxycycline, albuterol sulfate, glycopyrrolate, neostigmine methylsulfate, benazepril/ hydrochlorothiazide, Isuprel® (isoproterenol hydrochloride), and Nitropress® (nitroprusside).

104. Each letter stated:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community of Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients['] and pharmacies['] ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients."[21]

105. In addition to sending letters to the generic drug manufacturers listed above, Senator Sanders and Representative Cummings wrote a joint letter to Sylvia Burwell, the

[20] Ranking Members Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file.

[21] *See, e.g.*, Ltr. from Sen. Bernard Sanders & Rep. Elijah E. Cummings to Arthur P. Bedrosian (Oct. 2, 2014), http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file (citing Letter from B. Douglas Hoey to Sen. Tom Harkin, et al. (Jan. 8, 2014), https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf)).

Department of Health and Human Services Secretary, stating, "The federal government must act immediately and aggressively to address the increasing costs of these drugs."[22]

106. The Senate Subcommittee on Primary Health and Aging held a hearing on November 20, 2014. Although the Presidents and CEOs of Lannett, Teva, and Marathon Pharmaceuticals were scheduled to attend the hearing, none appeared. Many panelists agreed that reduced competition across various generic drugs has contributed to the price hikes observed in the overall market.

107. Subsequent congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, PharmD Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating, "When medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."[23]

108. On February 24, 2015, Senator Sanders and Representative Cummings wrote to Daniel R. Levinson, the Inspector General of the Department of Health and Human Services, imploring the department to "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare

[22] Congressional Panel to Probe Generic Drug Price Hikes (Nov. 11, 2014), http://www.sanders.senate.gov/newsroom/press-releases/congressional-panel-to-probe-generic-drug-price-hikes.

[23] Statement of Erin R. Fox, PharmD Director, Drug Information Service, Hearing on "Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines" (Dec. 9, 2015), at 7, http://www.aging.senate.gov/imo/media/doc/SCA_Fox_12_9_15.pdf.

and Medicaid programs."[24] On April 13, 2015, Inspector General Levinson responded to Senator Sanders and Representative Cummings's letter, stating that his office planned "to update our previous review of generic drug price increases under the Medicaid drug rebate program."[25]

B. Federal and State Antitrust Investigations into Generic Drug Pricing

109. Generic pricing patterns have also captured the attention of federal and state enforcement authorities in the United States. Generic drug manufacturers, including Defendant Taro, have received subpoenas or requests for information concerning their pricing of generic drugs, as well as their communications with their competitors for those drugs.

110. Initial reports suggest that, at the beginning, the probes were focused on two generic drugs: digoxin and doxycycline. However, recent news reports have confirmed the sweeping nature of the DOJ's investigation: at least two-dozen drugs and a dozen drug companies are under criminal investigation. Indeed, according to *Bloomberg* and other news agencies, DOJ's investigation has progressed to such a degree that the first criminal charges and indictments could be filed by the end of 2016.

111. A federal grand jury investigating the matter is empaneled in the Eastern District of Pennsylvania. The result of these investigations could result in the imposition of substantial fines and criminal pleas for generic manufacturers, and jail time for company executives. Some analysts have estimated that the DOJ could impose fines in excess of $1 billion.[26]

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[24] Letter from Hon. Bernard Sanders and Elijah Cummings to Hon. Daniel Levinson (Feb. 24, 2015), http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[25] Letter from Hon. Daniel Levinson to Hon. Bernard Sanders (Apr. 13, 2015), http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

[26] Eric Saonowsky, *DOJ's price-fixing investigation could lead to sizable liabilities, analyst says*, FiercePharma (Nov. 10, 2016), http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says.

112. To date, the following generic drug companies have been contacted in connection with both federal and state antitrust probes:

113. ***Lannett.*** In July 2014, Lannett revealed in SEC filings that they had received subpoenas from the CTAG in connection with its investigation into whether "anyone engaged in a contract, combination or conspiracy in restraint of trade or commerce which has the effect of (i) fixing, maintaining or controlling prices of digoxin or (ii) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law."[27]

114. The information and documents sought by the CTAG included: (1) the identification of "all persons at Lannett with any supervisory, executive or other significant non-ministerial responsibility related to the pricing or sale of Digoxin"; (2) the identification and production of "all documents or communications referring or relating to any decision(s), by you or any other company, to increase the price of Digoxin"; (3) the production of "[a]ll marketing plans, strategic plans or any other documents relating to the development, manufacture and commercialization of Digoxin"; and (4) the identification and production of "written compliance policy directed to the antitrust laws."

115. Five months later, on November 10, 2014, Lannett disclosed in an SEC filing that a senior sales and marketing executive was served with a DOJ grand jury subpoena "relating to a federal investigation of the generic industry into possible violations of anti-trust laws."[28]

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[27] Impax Laboratories (IPXL) Receives Subpoena from Connecticut AG, http://www.streetinsider.com/Corporate+News/Impax+Laboratories+(IPXL)+Receives+Subpoena+from+Connecticut+AG/9662945.html; Lannett Receive Inquiry from Connecticut Attorney General, http://finance.yahoo.com/news/lannett-receives-inquiry-connecticut-attorney-153300612.html.

[28] Ed Silverman, *Justice Department Probes Generic Companies After Price Hike Reports*, Wall. St. J. (Nov. 10, 2014).

116. On December 5, 2014, Lannett disclosed in a Form 8-K that it received another "grand jury subpoena related to the continuing federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act."[29] Lannett further disclosed that the "subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products."[30] In a 2015 SEC filing, Lannett further disclosed that the federal subpoenas requested information and documents for the period 2005 through the dates the subpoenas were issued.

117. ***Impax.*** In July 2014, Impax disclosed in received a subpoena from the CTAG concerning Impax's sales of generic digoxin and whether it agreed with others to fix prices or allocate customers or territories. In November 2014, Impax disclosed that it also received a federal grand jury subpoena requesting testimony and documents about "any communication or correspondence with any competitor about the sale of generic drugs."[31] The scope of the subpoenas was not limited to a particular drug or a particular timeframe.

118. Later, Impax further disclosed that on March 13, 2015, "the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular the Justice Department's investigation currently focuses on four

[29] Lannett Form 8-K (Dec. 5, 2014), http://www.sec.gov/Archives/edgar/data/57725/000110465914085406/a14-25827_18k.htm.

[30] *Id.*

[31] Impax SEC Form 8-K (Nov. 6, 2014), https://www.sec.gov/Archives/edgar/data/1003642/000119312514402210/d816555d8k.htm.

generic medications: digoxin, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution."[32]

119. ***Par.*** The federal grand jury's probe continues to expand. In an SEC Form 10-K for 2014, Par disclosed that it had received a subpoena from DOJ "requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets and our generic doxycycline products."[33] Moreover, in that same filing Par revealed that the CTAG served a subpoena on Par on August 6, 2014 "requesting documents related to our agreement with Covis Pharma S.a.r.l. to distribute an authorized generic version of Covis's Lanoxin® (digoxin) oral tablets."[34] Par stated that it completed its response on October 28, 2014.

120. ***Actavis.*** Actavis's parent Allergan plc also disclosed in public filings that they received subpoenas from DOJ. Allergan reported that, on June 25, 2015, Actavis received a subpoena from DOJ "seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."[35]

121. ***Mylan.*** Mylan similarly disclosed in a 2016 SEC filing that it received a subpoena from DOJ "seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products."[36] Mylan received a similar subpoena from the CTAG, seeking "information relating to the marketing,

[32] Impax, SEC 2015 Form 10-K, at F-53.

[33] Par Pharmaceuticals Companies, Inc., SEC 2014 Form 10-K, at 37.

[34] *Id.*

[35] Allergan, SEC 2015 Form 10-K, at F-106.

[36] Mylan, SEC 2015 Form 10-K, at 160.

pricing and sale of certain of the Company's generic products (including Doxycycline) and communications with competitors about such products."[37]

122. More recently, on November 10, 2016, Mylan disclosed that DOJ issued a subpoena to Mylan and certain employees and senior management "seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products."[38] Significantly, Mylan disclosed that "[r]elated search warrants also were executed" in connection with DOJ's investigation.[39]

123. ***Sun.*** On or about May 28, 2016, Sun disclosed that it had received a subpoena from DOJ "seeking information about the pricing and marketing of the generic drugs it sells in the United States."[40] DOJ also sought documents related to "employee and corporate records and communications with competitors."[41]

124. ***Dr. Reddy's***. On or about August 11, 2016, Dr. Reddy's disclosed in an SEC filing that it had received a subpoena from the DOJ on July 6, 2016, "seeking information relating to the marketing, pricing and sale of certain . . . generic products and any communications with competitors about such products."[42] In that same filing, Dr. Reddy's disclosed that it had received a subpoena from the CTAG concerning the same matters.

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[37] *Id.*

[38] Mylan SEC Form 10-Q, at 58 (Nov. 10, 2016), http://apps.shareholder.com/sec/viewerContent.aspx?companyid=ABEA-2LQZGT&docid=11678486#MYL10Q_20160930XDOC_HTM_S582E80BDD4215D11A4040D12D4C2E297.

[39] *Id.*

[40] India's Sun Pharma Gets U.S. Subpoena Over Generic Drugs Pricing, Fortune (May 28, 2016), http://fortune.com/2016/05/28/sun-pharma-drug-price-subpoena.

[41] *Id.*

[42] Dr. Reddy's, SEC Form 6-K (Aug. 31, 2016).

125. ***Mayne.*** In its 2016 Annual Report, Mayne Pharma Ltd. disclosed that it was "one of numerous generic pharmaceutical companies to receive a subpoena form the Antitrust Division of the US Department of Justice [] in the last two years seeking information relating to marketing, pricing and sales of select generic drugs."[43] In the same Annual Report, Mayne Pharma also disclosed that it had received a subpoena from the CTAG seeking similar information.

126. ***Teva.*** On August 4, 2016, Teva disclosed that "[o]n June 21, 2015, Teva USA received a subpoena from the Antitrust Division of the United States Department of Justice seeking documents and other information relating to the marketing and pricing of certain of Teva USA's generic products and communications with competitors about such products."[44] In that same filing, Teva disclosed that on July 12, 2016, "Teva USA received a subpoena from the Connecticut Attorney General seeking documents and other information relating to potential state antitrust law violations."[45]

127. ***Taro.*** On September 9, 2016, Taro disclosed that on September 8, 2016, it and two senior officers in Taro's commercial team, "received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with

[43] Mayne Pharma, 2016 Annual Report, at 75.

[44] Teva, SEC Form 6-K at 25 (Aug. 4, 2016), http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMDcyODU1JkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3.

[45] *Id.*

competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."[46]

128. ***Zydus.*** Although Zydus is not publicly traded in the United States and thus not subject to reporting requirements under federal securities laws, recent press reports have stated the Zydus is also a target of the DOJ's sweeping investigation.[47] According to one article, Zydus is being investigated in connection with its marketing and sale of divalproex ER.[48]

ANTITRUST IMPACT

129. During the relevant period, Plaintiff and members of the Classes purchased substantial amounts of clobetasol indirectly from Defendants. As a result of Defendants' illegal conduct, these purchasers have paid, and continue to pay, artificially inflated prices for clobetasol. The prices paid were substantially higher than the prices that Plaintiff and members of the Classes would have paid absent the illegal conduct alleged in this Complaint.

130. As a consequence, purchasers of clobetasol have sustained substantial losses and damage to their business and property in the form of overcharges—and their losses continue to date. The full amounts, forms, and components of such damages will be calculated after discovery and upon proof at trial.

131. Defendants' efforts to restrain competition in the market for clobetasol have substantially affected intrastate and interstate commerce—and continue to do so.

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[46] Taro, SEC Form 6-K (Sept. 9, 2016), http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjUwJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3.

[47] Rupali Mukherjeel, *US polls, pricing pressure may hit Indian pharma cos*, The Times of India, http://timesofindia.indiatimes.com/business/india-business/US-polls-pricing-pressure-may-hit-Indian-pharma-cos/articleshow/55301060.cms.

[48] *Hillary win may pose pricing challenges for pharma cos: Report*, F. World (Nov. 7, 2016), http://www.firstpost.com/world/hillary-win-may-pose-pricing-challenges-for-pharma-cos-report-3093544.html.

132. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of clobetasol in a continuous and uninterrupted flow of commerce throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase because, among other things, consumers and third-party payors within each state were forced to pay supracompetitive prices for clobetasol.

133. At all times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of clobetasol.

134. Economists recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top.[49] He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[50]

135. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of clobetasol to Plaintiff and members of the Classes.

136. Defendants' anticompetitive conduct enabled Defendants to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants' unlawful actions.

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[49] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

[50] *Id.*

137. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

138. The inflated prices that Plaintiff and members of the Classes have paid for clobetasol, and continue to pay, are traceable to and the foreseeable result of, the overcharges by Defendants.

CLASS ALLEGATIONS

139. Plaintiff brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(2), on behalf of itself and a nationwide class of similarly situated individuals seeking injunctive and equitable relief:

> **The Injunctive Class**:
>
> All persons or entities in the United States and its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for clobetasol, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as June 3, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

140. Plaintiff also brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of itself and a class of similarly situated individuals seeking damages arising from Defendants' conduct as described below:

> **The Damages Class**:
>
> All persons or entities who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for clobetasol, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as June 3, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased, in any of the following states, commonwealths, and territories: Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota,

Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia.

141. The following persons and entities are excluded from the above-described Classes:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit plans;

(c) All persons or entities who purchased clobetasol for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and

(f) The judges in this case and any members of their immediate families.

142. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that there are thousands of members of each Class.

143. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and members of the Classes were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for clobetasol as a result of Defendants' wrongful conduct—and continue to do so.

144. Plaintiff will fairly and adequately protect and represent the interests of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

145. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

146. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to each member of the Injunctive Class and Damages Class.

147. Questions of law and fact common to members of both Classes include:

(a) the identity of the participants in the conspiracy;

(b) whether Defendants conspired to fix, raise, maintain, and stabilize the prices of clobetasol;

(c) whether Defendants conspired to allocate markets or customers with respect to the clobetasol;

(d) whether Defendants' conduct harmed competition in the clobetasol market;

(e) whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;

(f) whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Classes in the nature of overcharges;

(g) the amount of overcharges paid by Plaintiff and members of the Classes in the aggregate; and

(h) the injunctive and other equitable relief needed to end Defendants' restraint and to restore competition in the clobetasol market.

148. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

149. Plaintiff knows of no special difficulty to be encountered in this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of Sherman Act § 1, 15 U.S.C. § 1
(By Plaintiff and Injunctive Class Members Against All Defendants)

150. Plaintiff incorporates the preceding paragraphs by reference.

151. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of clobetasol, and allocate markets and customers for clobetasol—and continue to do so.

152. Had Defendants competed instead of conspiring to restrain trade, Plaintiff and Injunctive Class Members would have paid substantially lower prices for clobetasol.

153. Defendants intended, and accomplished, a price-fixing conspiracy and horizontal market allocation of the market for clobetasol, which are *per se* violations of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a

result of this unreasonable restraint on competition, Plaintiff and Injunctive Class Members paid artificially inflated prices for clobetasol—and continue to do so.

154. Plaintiff and Injunctive Class Members have suffered harm, and are continuing to suffer harm, as a result of paying higher prices for clobetasol than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreements. Plaintiff and Injunctive Class Members also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

155. Plaintiff and Injunctive Class Members have purchased substantial amounts of clobetasol indirectly from Defendants.

156. Plaintiff and Injunctive Class Members seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that Defendants' conduct violates Section 1 of the Sherman Act.

157. Plaintiff and Injunctive Class Members also seek equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

State Antitrust Violations
(By Plaintiff and Damages Class Members Against All Defendants)

158. Plaintiff incorporates the preceding paragraphs by reference.

159. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of clobetasol and allocate markets and customers for clobetasol—and continue to do so.

160. Defendants' unlawful conduct harmed Plaintiff and Damages Class Members in the manner explained above.

161. Defendants' unlawful conduct covered a sufficiently substantial percentage of the relevant market to harm competition.

162. Defendants' actions constitute horizontal market allocation and price-fixing agreements between actual and potential competitors and are illegal *per se* under state antitrust laws.

163. Defendants' supracompetitive pricing constitute a continuing violation of the laws of the states listed below in that each purchase by Plaintiff or a member of the Damages Class of supracompetitively priced clobetasol caused injury to their business or property—and continue to do so.

164. Defendants' conduct violated the following state laws:

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Damages Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Damages Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Damages Class;

(e) Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class;

(f) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Damages Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Damages Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Damages Class;

(i) Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class;

(j) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Damages Class;

(k) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Damages Class;

(l) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class;

(m) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class;

(n) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class;

(o) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Damages Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Damages Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Damages Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Damages Class;

(u) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class;

(v) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Damages Class;

(w) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class;

(x) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Damages Class;

(y) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Damages Class;

(z) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class; and

(aa) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Damages Class.

165. Plaintiff and Damages Class Members have been and continue to be injured in their business or property by Defendants' antitrust violations. Their injuries consist of: (1) being denied free and open competition between competitors in the market for clobetasol; and (2) paying higher prices for clobetasol than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

166. Plaintiff and Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

167. Defendants are jointly and severally liable for all damages suffered by Plaintiff and Damages Class Members.

168. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

THIRD CLAIM FOR RELIEF

Unjust Enrichment
(By Plaintiff and Damages Class Members Against All Defendants)

169. Plaintiff incorporates the preceding paragraphs by reference.

170. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

171. Defendants have benefited and continue to benefit from the overcharges on sales of clobetasol made possible by the unlawful and inequitable acts alleged in this Complaint.

172. Defendants' financial benefits are traceable to Plaintiff's and Damages Class Members' overpayments for clobetasol.

173. Plaintiff and Damages Class Members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and Damages Class Members.

174. It would be futile for Plaintiff and Damages Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and Damages Class Members.

175. It would be futile for Plaintiff and Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased clobetasol, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class Members for Defendants' unlawful conduct.

176. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for clobetasol is a direct and proximate result of Defendants' unlawful practices.

177. The financial benefits Defendants derived rightfully belong to Plaintiff and Damages Class Members, who paid, and continue to pay, anticompetitive prices that inured to Defendants' benefit.

178. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia for Defendants to retain any of the overcharges Plaintiff and Damages Class Members paid for clobetasol that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

179. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Damages Class.

180. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Damages Class Members.

181. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff and Damages Class Members.

182. Plaintiff and Damages Class Members have no adequate remedy at law.

DEMAND FOR JUDGMENT

Accordingly, Plaintiff, on its own behalf and on behalf of the proposed Classes, demands judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to members of the Classes under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Classes;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other state statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters judgment against Defendants joint and severally and in favor of Plaintiff and the Classes;

E. Grants Plaintiff and the Injunctive Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. Awards the Plaintiff and the Damages Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

Dated: December 5, 2016

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